

**NASAL DECONGESTANT PE MAXIMUM STRENGTH- phenylephrine hcl tablet, coated**  
**Cardinal Health**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Leader 44-453**

***Active ingredient (in each tablet)***

Phenylephrine HCl 10 mg

***Purpose***

Nasal decongestant

***Uses***

- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- temporarily relieves sinus congestion and pressure

***Warnings***

**Do not use**

if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if you have**

- diabetes
- heart disease
- high blood pressure
- thyroid disease
- difficulty in urination due to enlargement of the prostate gland

**When using this product**

**do not exceed recommended dosage.**

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or occur with fever

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away.

***Directions***

- adults and children 12 years and over: take 1 tablet every 4 hours. Do not take more than 6 tablets in 24 hours.
- children under 12 years: ask a doctor

***Other information***

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

***Inactive ingredients***

croscarmellose sodium, dextrose monohydrate, dibasic calcium phosphate dihydrate, FD&C red #40, lecithin, magnesium stearate, maltodextrin, microcrystalline cellulose, silicon dioxide, sodium carboxymethylcellulose, sodium citrate dihydrate, titanium dioxide

***Questions or comments?***

**1-800-426-9391**

***Principal display panel***

**LEADER™**

NDC 70000-0126-2

Maximum Strength | Non-Drowsy

**Nasal**

**Decongestant PE**

**Phenylephrine HCl, 10 mg** | Nasal Decongestant

Sinus Pressure + Congestion

Pseudoephedrine-Free

**72 TABLETS**

Actual size

COMPARE TO SUDAFED PE® CONGESTION MAXIMUM STRENGTH active ingredient\*  
100% Money Back Guarantee

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS  
TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**

\*This product is not manufactured or distributed by Johnson & Johnson Corporation,  
owner of the registered trademark Sudafed PE® Congestion Maximum Strength.

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**CardinalHealth™**

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com 1-800-200-6313

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respective owners.

All LEADER™ Brand Products Have A

**100% Money Back Guarantee**

Return to place of purchase if not satisfied.

**NASAL DECONGESTANT PE MAXIMUM STRENGTH**  
phenylephrine hcl tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0126
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients	
Ingredient Name	Strength
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>DEXTROSE MONOHYDRATE</b> (UNII: LX22YL083G)	
<b>CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE</b> (UNII: O7TSZ97GEP)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	

Product Characteristics			
Color	red	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	44;453
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0126-1	1 in 1 CARTON	01/14/2005	
1		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70000-0126-2	3 in 1 CARTON	01/14/2005	
2		24 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information
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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/14/2005	

**Labeler** - Cardinal Health (097537435)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(70000-0126)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(70000-0126)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(70000-0126)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(70000-0126)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	pack(70000-0126)

Revised: 4/2021

Cardinal Health